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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

January 24, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
CIN-WL-00-600

Donna M. Richardson
President/Chief Operating Officer
NeuroControl Corp.
8333 Rockside Road
Valley View, OH 44125-6104

Dear Ms. Richardson:

We are writing to you because during an inspection of your firm located at the above address by the Food and Drug Administration (FDA) on October 20, 1999/November 3, 1999, our Investigator collected information that revealed serious regulatory problems involving the NeuroControl Freehand System which is manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a medical device. The law requires that manufacturers of medical devices conform with the requirements of the Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that the device is adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the requirements of the Quality System Regulation as follows:

Failure to maintain adequate corrective and preventive action procedures. Not all sources of quality data are analyzed to identify existing and potential causes of nonconforming product and other quality problems. For example, there is no documentation that field reports that involved user injury, potential injury, or abnormal failures were reviewed and evaluated as potential complaints and where investigated where necessary.

Failure to establish and maintain procedures to ensure that the device design is correctly translated into production specifications as required by 21 CFR 820.30(h). For example, after several design changes, two ([redacted] lots of Epimysial Electrodes (s/l # [redacted] and [redacted]) and three ([redacted]) lots of Electrode Positioning Kits (s/l # [redacted]) have been released to distribution without the following documents being completed and approved:

a. the Device Master Records (or BCL, Build Configuration List),
b. Incoming Acceptance Procedures,
c. documented final design changes, and
d. Engineering Change Notices (ECOs).

The FDA inspection also revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act. Your firm failed to submit information to the FDA as required by the Medical Devices: Reports of Corrections and Removals Regulation, as specified in 21 CFR Part 806.

Specifically, your firm failed to notify FDA within 10 working days after initiating the removal of the Epimysial Electrodes used with the Freehand System. The removal was initiated on11/13/98 and was completed on 2/8/99. Information regarding the field correction/removal was collected during the above mentioned FDA inspection and submitted to the FDA, Cincinnati District Recall Coordinator by the FDA Investigator during the course of the FDA inspection. The recall was classified by FDA as a class II recall (Z-01320).

We received your letter dated November 4, 1999 regarding the removal of Freehand Epimysial Electrodes. We noted that your firm failed to include the information specified in 21 CFR 806.10(c)(10), (11) and (12). Attached for your information is a guidance document entitled "Medical Devices: Reports of Corrections and Removals Guidance".

We also received your letters dated November 10, 1999 and December 14, 1999 in response to a FDA 483 dated November 3, 1999 that was issued to management at your firm. Your response was not adequate to correct all of the violative conditions at your firm. As explained in this letter, your Corrective and Preventive Action Procedures and Design Control Procedures do not appear to be adequate. For example, we noted that your revised recall procedure does not address the requirements of 21 CFR 806.10(c) or 806.20. Your response did not address any specific actions your firm took with regard to performing a failure investigation for Report # [redacted] dated [redacted] which appeared to be a complaint involving the possible failure of a device to meet its specifications. You did not indicate the specific corrective actions taken with respect to updating the documents for the devices discussed above that were distributed without completed and approved documents.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the FDA inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by The Food and Drug Administration without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Road, Cincinnati, Ohio 45237.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District

Attachment